

Remarks

In response to the Office Action mailed October 19, 2007, Applicants submit the following remarks. The statutory deadline for filing a response is January 19, 2008. Therefore, Applicants believe that this response is being timely filed. Applicants also submit herewith a Request for Continued Examination (RCE) and the appropriate fee. The RCE is submitted to allow entry and consideration of the above amendments. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-754.201.

By the above amendment, the claims have been revised to recite a method wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds. This amendment is supported throughout the specification as originally filed. See for example the discussion in connection with Figure 8 in paragraph [0061]. Accordingly, the amendment is proper and entry thereof is respectfully requested.

Claim Rejections – 35 U.S.C. §103

Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Szumski et al. (3,470,011). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Palmer (6,537,242). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Powell (6,589,202). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 96/10630. Claims 18-24, 29-35 and 4 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ginaven et al. (5,457,041). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cormier et al. (US2002/0102292). These rejections are traversed for at least the following reasons.

The rejections under 35 U.S.C. 103(a) raise similar issues and are therefore addressed as a group.

As defined by present Claim 18, the subject invention relates to a method of making a device for transdermally delivering a pharmacologically active agent, the

method comprising: providing a member having a plurality of stratum corneum-piercing microprotrusions; applying an aqueous solution of the pharmacologically active agent onto the member; and drying said applied aqueous solution to form a dry agent-containing coating on said member. The agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises. The coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds. And, the method provides uniformity of coating from microprotrusion to microprotrusion.

None of the references relied upon in the Office Action provide the requisite guidance to achieve the claimed method for preparing a member having a plurality of stratum corneum-piercing microprotrusions having a dry agent-containing coating, wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds. Thus, none of the references, taken alone or in combination, suggest the presently claimed method.

Accordingly withdrawal of the rejections under 35 U.S.C. 103(a) based on Szumski et al, Palmer, Powell, WO 96/10630, Ginaven et al., and Cormier et al. is respectfully requested.

Provisional Double Patenting

Claims 18-24, 29-35 and 47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 54-64 of copending U.S. Application No. 11/034,891. Claims 18-24, 29-35 and 47 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 28-54 of copending U.S. Application No. 10/127,108, over claims 21-39 of copending U.S. Application No. 10/674,626, over claims 10-13 of copending U.S. Application No. 10/972,231, claims 33-38 of copending U.S. Application No. 11/201,625, claims 32-34 of copending U.S. Application No. 11/206,698 and claims 30-35 of copending U.S. Patent Application No. 11/355,856.

Applicants note with appreciation indication in the Office Action that the double patenting rejection is stayed in abeyance until the subject application is indicated to be otherwise in condition for allowance.

CONCLUSION

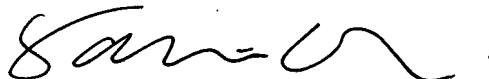
Applicants believe that, for the reasons explained above, all of the pending claims are in condition for allowance and such favorable action is respectfully requested. Applicants believe that this response is being timely filed. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-754.201.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

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Respectfully submitted,

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